

EXHIBIT A

10 The deposition of LARRY T. SIRLS, II, M.D.,
11 Taken at 41000 Woodward Avenue, Suite 200 East,
12 Bloomfield Hills, Michigan,
13 Commencing at 9:33 a.m.,
14 Thursday, July 21, 2016,
15 Before Cheryl McDowell, CSR-2662, RPR.

1 things that are informative.

2 Q. Okay. But I'm asking you a different question, so
3 let's focus on that.

4 A. Okay.

5 Q. I'm not asking you whether it's informative. What
6 I'm asking you, is it your opinion that this IFU
7 that predates 2015 for the Gynecare TTV was adequate
8 to advise physicians of the risks associated with
9 the TTV device?

10 A. As a pelvic surgeon, I know all of these things. So
11 these things, this is adequate for me because my
12 knowledge base augments and supersedes this
13 information. So I find this to be adequate.

14 Q. Okay. Are you speaking only for yourself based on
15 your knowledge base?

16 A. Myself, my partners, my fellows, my residents. I
17 mean, those of us who do this know this.

18 Q. But you realize there's lots of doctors who implant
19 the TTV that go beyond you, your partners, your
20 fellows, and your residents, right?

21 A. Sure.

22 Q. A whole lot of doctors around this country who are
23 implanting and have implanted the TTV device into
24 women?

1 A. Yes.

2 Q. Okay. Do you believe as a general proposition that
3 this Gynecare TVT IFU from pre-2015 was adequate to
4 warn physicians, all the physicians who are
5 implanting TVT devices into women, of the risks
6 associated with the TVT device?

7 A. Yes.

8 MS. FITZPATRICK: Okay. And let's take a
9 look then, we'll mark this as Exhibit 12.

10 (Sirls TVT-12 marked and attached.)

11 BY MS. FITZPATRICK:

12 Q. The Gynecare TVT Obturator System Instructions For
13 Use that Ethicon put out prior to 2015.

14 You've seen this document before, right?

15 A. Yes.

16 Q. And is it your opinion, Doctor Siris, that the TVT
17 IFU prepared by Ethicon prior to 2015 was adequate
18 to advise physicians as a whole on the risks
19 associated with the TVT device?

20 A. Yes. It's the same adverse reaction list.

21 Q. Okay. Now, I want you to put Exhibits 10, 11, and
22 12 in front of you.

23 A. Okay.

24 Q. And we discussed at page eleven of Doctor Schimpf's

1 article where she's discussing the differences in
2 the risk profiles for the retropubic and the
3 obturator mid-urethral slings, right?

4 A. Yes.

5 Q. And that was information that you agreed with
6 Doctor Schimpf and you agreed that you provided to
7 your patients, correct?

8 A. I give about a forty-five minute discussion to every
9 patient I do a sling on, so I cover all these things
10 and more.

11 Q. Okay. Can you show me in Exhibit 11 and Exhibit 12
12 where Ethicon tells physicians that there is a
13 different risk profile for a retropubic TTV device
14 and an obturator TTV-O device?

15 A. Ethicon doesn't need to tell physicians that. We
16 know that. It's a different approach. I mean,
17 you've got an abdominal approach, you've got an
18 obturator approach. They're inherently different
19 procedures. We know they have different risk
20 profiles.

21 Q. Can I ask you, if everybody knows that, why did
22 Doctor Schimpf and her colleagues and hundreds of
23 other physicians, why have they spent their time
24 studying the differences between retropubic and

1 obturator mid-urethral slings if everybody just
2 knows it anyhow?

3 A. Well, these are really great documents and
4 meta-analyses of the literature, et cetera, and what
5 they do is they review all the available
6 information, and they report it kind of like a
7 computer. You report information that is
8 interesting and helpful, and you report information
9 that might not be interesting, information that
10 everybody knows already.

11 Q. So Doctor Schimpf and her colleagues wasted their
12 time because they reported on stuff that all of you
13 already knew? This is like telling physicians that
14 the sky is blue. Why would you tell them?

15 MR. KOOPMANN: Object to form.

16 THE WITNESS: I don't agree with that.
17 These are -- this is a very specific table. It's
18 guidelines. And what they're doing is they're
19 trying to just help the reader understand all these
20 different procedures.

21 This table is not just about these two
22 approaches. It's about all these different
23 procedures. They're being very general, and they're
24 making general comments that are intuitive.

1 Transobturator slings have, you know, more groin
2 pain than retropubic sling.

3 BY MS. FITZPATRICK:

4 Q. Let's stop it there.

5 A. Sure.

6 Q. Did Ethicon tell anybody that in these Instructions
7 For Use prior to 2015?

8 A. Surgeons who are putting a trocar through the
9 obturator foramen don't need the company to tell
10 them that it can cause groin and leg pain.

11 Q. Okay. So this is where I'm really not understanding
12 what you're saying. You're saying that the company
13 doesn't need to tell physicians that there's a
14 difference in the risk profile, correct? Just is
15 that what you're telling me?

16 A. I'm sorry. The question again?

17 Q. You're saying that the company doesn't need to tell
18 physicians that there's a difference in the risk
19 profile between the TVT and the TVT-O.

20 A. I'm saying that these things that we're mentioning
21 here are intuitive to surgeons, and they don't need
22 an IFU.

23 Q. Why do you and your colleagues spend so much time or
24 perhaps waste so much time putting together medical